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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,108	06/24/2003	Gary L. Breton	PATH03-14	2547

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,108	BRETON, GARY L.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/15/06, 6/12/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

Applicants' election of Group I (claims 1-10 drawn to nucleic acids) and SEQ ID NO:1298 (encoding the amino acid sequence of SEQ ID NO:3218) in the response filed 6/12/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-28 are currently pending, claims 1-10 are under examination. Claims 11-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

It is noted that applicant in the response appears to assert that the election of the sequence of SEQ ID NO:1298 is a "species" election "for searching purposes." See pages 1 and 2 of the response filed 6/12/06. Applicant is reminded that it was explicitly point out that the restriction requirement set forth in the previous Office action including the sequence election requirement was not a species election requirement, but election among patentably distinct groups of inventions for reasons set forth on pages 5-6 of the previous Office action mailed 12/9/05.

The amendments to the claims filed 11/15/06 are acknowledged and entered.

The preliminary amendments filed 6/24/03 are acknowledged and entered.

Information Disclosure Statement

The Information Disclosure Statement filed 6/24/03 has been entered and documents therein have been considered. Initialed copy of the form PTO-1449 is herein enclosed.

Specification

The specification is objected to because of the following including informalities:

The title of the invention is not descriptive. The elected invention is drawn to polynucleotides. The current title, however, is directed to nucleic acids and amino acid relating to M. catarrhalis for diagnostics and therapeutics. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Trademarks are used in this application, such as GENBANK at least on page 45. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because of the following informalities:

It seems that the "andORF's" recited on page 26, line 30, should be "and ORF's;" and the "Altschal et al., 1990, L Mol. Biol. 215: 403-410" recited in line 29 of the same page should be "**Altschul** et al., 1990, **J.** Mol. Biol. 215: 403-410."

Appropriate correction is required.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claims 1-10 are drawn to nucleic acids having a nucleotide sequence of SEQ ID NO: 1298 or a sequence encoding the amino acid sequence of SEQ ID NO:3218, or recombinant vectors comprising the nucleic acid or cells comprising the recombinant vectors. The claimed nucleic acid is not supported by a specific asserted utility because none of the disclosed uses of the nucleic acid in the specification is specific and substantial. For example, the specification throughout states that the nucleic acids disclosed can be used as a probe for diagnosis of M. catarrhalis bacteria or diseases caused thereby. However, the use is not specific to the nucleic acid of SEQ ID NO:1298 but generic to thousands of sequences of SEQ ID NOs:1-1920. Furthermore, it would be readily recognized by one skilled in the art that for a nucleic acid to be used as a probe for diagnosis of the bacterium M. catarrhalis or diseases caused thereby, the nucleic acid has to be specific only to M. catarrhalis, without cross-hybridization to other organisms. However, this is hardly the case for the sequence of SEQ ID NO:1298. Wedler et al. disclose a yeast nucleic acid sequence (GenBank accession number Z72861) that contains a sequence that is identical to a stretch of 21 consecutive nucleotides of SEQ ID NO:1298. See the attached sequence alignment between SEQ ID NO:1298 and Z72861, the result of an oligomer search. It would be readily apparent to one skilled in the art that such a sequence with 21 consecutive nucleotides identical to that stretch of the instant SEQ ID NO:1298 would cross-hybridize to the latter under relatively low stringency and even under high stringencies. Thus, using the sequence as a probe would have cross-hybridization to sequences of other organisms

even under stringent conditions. It would require further research to determine a specific sequence, if any, for M. catarrhalis that is unique only to the organism so that it would be able to be used as a probe for diagnosis for M. catarrhalis. Recently, in *In re Fisher,* a case analogous to the present application, the court, following an analysis of Nelson, 626 F.2d at 856, with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polynucleotide is useful as a probe for the diagnosis of M. catarrhalis to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide encoded by SEQ ID NO:1298 such that another non-asserted utility would be well established for the claimed nucleic acid.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 8 and 10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 8 is drawn to a method for producing an M. catarrhalis polypeptide encoded by the nucleic acid sequence of claim 5. Claim 5 is drawn to a complement of SEQ ID NO:1298. While the specification discloses that SEQ ID NO:1298 encodes a polypeptide of SEQ ID NO: 3218, it does not adequately describe that its complement also encodes a polypeptide.

Claim 10 is drawn to nucleic acid molecules having a sequence of at least eight nucleotides in length and is hybridizable to a nucleic acid having the sequence of SEQ ID NO:1298 or its complements.

The claim is rejected mostly for the same reasons as those set forth in the "Revised Interim Written Description Guidelines Training Material" for similar claim limitations. The training material is available on the US PTO's website: http://www.uspto.gov/web/patents/guides.htm.

The claim is drawn to a genus of polynucleotides including any nucleic acids of at least eight nucleotides in length that are hybridizable to SEQ ID NO:1298 or its complements. Since the claim does not specify any stringency conditions for the hybridization, and does not contain functional limitations, the claim is broad and reads on virtually any nucleic acids because almost any nucleic acid will hybridize to a nucleic acid having the sequence of SEQ ID NO:1298 at certain conditions such as that of extremely low stringency. Clearly, there is substantial

variability among the species encompassed by the scope of the claim because the genus encompasses a variety of species with different structures and distinct functions.

A description of a genus may be achieved by means of a recitation of a representative number of species, falling within the scope of the genus, or by means of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, the specification discloses only a species: the nucleotide sequence of SEQ ID NO:1298, but, as set forth above, the lack of stringency of hybridization conditions and the lack of functional limitation would be expected to yield structurally unrelated nucleic acid molecules. Thus, the single disclosed species is not representative of the genus because there is no structural attribute or feature that is common to the members of the genus.

Therefore, one skilled in the art would reasonably conclude that applicant was not in possession of the claimed genus because a description of only one member of the genus is not representative of the broad genus of claimed invention.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wedler et al. (Database sequence GenBank accession number Z72861, version Z72861.1, 8/11/1997).

The claims are drawn to a polynucleotide comprising a sequence that has at least eight contiguous nucleotides of the sequence of SEQ ID NO:1298 (claim 9) or that is hybridizable to the sequence of SEQ ID NO:1298 (claim 10).

Wedler et al. in the database disclose a nucleic acid comprising a sequence (Z72861) that that has a sequence that is identical to a stretch of 21 consecutive nucleotides of SEQ ID NO:1298. See the attached sequence alignment. It would be readily apparent to one skilled in the art that the sequence of Z72861 would hybridize to SEQ ID NO:1298 at least under extremely low stringent hybridization condition, e.g. in a refrigerator.

Note that in this Office action, the phrase "a complement of SEQ ID NO:1298" recited in claim 5, line 3, and in claim 9, line 4, is construed as the complete complement of SEQ ID NO:1298 and not including any nucleic acid that is partially complementary to SEQ ID NO:1298.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER